

R E M A R K S

Claims 1 to 5 as set forth in Appendix II of this paper are now pending in this case. Claim 6 has been canceled and Claims 1 and 2 have been amended as indicated in the Listing of Claims set forth in Appendix I of this paper.

Accordingly, applicants have made some editorial changes in the language of Claim 1, and have revised Claim 1 to better bring out the essential characteristics of a planetary roller extruder which are addressed on page 3, indicated lines 23 to 28, of the application. Claim 2 has been revised accordingly. No new matter has been added.

The Examiner has objected to the specification for not containing an abstract. Applicants herewith submit a substitute Abstract. Withdrawal of the respective objection is therefore solicited.

The Examiner has rejected Claim 6 under 35 U.S.C. §102(b) as being anticipated by the disclosure of **Newton** (US 5,683,719). Applicants have canceled Claim 6, and withdrawal of the respective rejection is respectfully solicited.

The Examiner has rejected Claims 1 to 5 under 35 U.S.C. §103(a) as being unpatentable in light of the disclosure of **Breitenbach et al.** (US 6,221,368) when taken in view of the teaching of **Newton** and **Muller** (US 4,268,176). In this context, the Examiner takes the position that the disclosure of **Newton**¹⁾

The extrusion process may be carried out using equipment and techniques which are known in the art of extrusion processing. Examples of extrusion equipment which may be utilized include end plate extruders, screen extruders, rotary cylinder extruders, rotary gear extruders and ram extruders.

provides a teaching to utilize a planetary roller extruder as required in accordance with applicants' method. The Examiner particularly points in this regard to the rotary cylinder extruders mentioned in the cited section.

It is respectfully urged that a planetary roller extruder does not comprise a rotating cylinder, and the rotary cylinder extruder

1) Col. 4, indicated line 3 et seq., of US 5,683,719.

mentioned by **Newton** can therefore not be considered to teach the use of a planetary roller extruder. **Newton** further mentions rotary gear extruders. The expression "rotary gear extruder" is, however, so generic that it encompasses all extruders which comprise a rotating internal "gear", ie. needle extruders as well as any single-, twin- or multi-screw extruder. As such, the statements made by **Newton** in the above-cited section are by far too generic to direct a person of ordinary skill in the art to a planetary roller extruder. It is also respectfully noted that the extruder employed by **Newton** in the representative examples is a ram extruder. Ram extruders are understood in the art as piston plastication units.

The Examiner has applied the teaching of **Muller** as evidence that a planetary roller extruder is a type of multi-screw extruder. As such, the planetary roller extruder falls within the conventionally known types of extruders.

Obviousness under Section 103(a) can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art²⁾. The mere fact that references can be combined or modified as is necessary to arrive at the invention as claimed does not render the resultant combination obvious where the prior art fails to suggest the desirability of the particular combination³⁾. Neither the teaching of **Breitenbach et al.** nor the teaching of **Newton** or the knowledge generally available in the art provide an incentive to pick a planetary roller extruder as disclosed by **Muller** from the myriad of conventional extruders in order to process a composition comprising a polymeric binder, at least one active pharmaceutical agent and optionally further additives. As such, the teaching, suggestion, or motivation to do what applicants have done is absent. The teaching of **Breitenbach et al.** when taken in view of the disclosure of **Newton** and **Muller** is, therefore insufficient to establish that applicants' invention was obvious within the provi-

2) In re Kotzab, 217 F.3d 1365, 55 USPQ2d 1313 (CAFC 2000). See also In re Lee, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (CAFC 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (CAFC 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (CAFC 1992).

3) In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (CAFC 1990). See also In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780 (CAFC 1992).

sions of Section 103(a) when it was made. Favorable reconsideration of the Examiner's position and withdrawal of the rejection under Section 103(a) is, therefore, respectfully solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a three month extension of time be granted in this case. A check for the \$950.00 fee is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF



Daniel S. Kim

Reg. No. 51,877

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)
THE CURRENT CLAIMS (Appendix II)
THE SUBSTITUTE ABSTRACT (Appendix III)

HBK/BAS

03/10/2004 GWKDDOF1 00000044 09057054

01 FC:1253

950.00 DP

A P P E N D I X I:

THE LISTING OF CLAIMS (version with markings):

1. (currently amended) A method for producing solid forms of administration by melt extrusion, ~~[wherein]~~ which comprises mixing and melting a polymeric binder, at least one active pharmaceutical agent and~~[, if required,]~~ optionally further additives ~~[are mixed]~~ in an extruder ~~[and melted]~~, and subsequently ~~[extruded]~~ extruding the melted mixture in a continuous ductile production string, ~~[characterized in that]~~ wherein the extruder is a planetary roller extruder (10) [is used as the extruder] comprising a bushing, a central spindle housed in said bushing and planetary spindles freely rotating in a rolling-off process between said bushing and said central spindle.
2. (currently amended) The method in accordance with claim 1, characterized in that a planetary roller extruder (10) with ~~[a central spindle (13) and]~~ three to eight planetary spindles (14) ~~[are]~~ is used.
3. (original) The method in accordance with claim 2, characterized in that a planetary roller extruder (10) with six planetary spindles (14) is used.
4. (original) The method in accordance with claim 1, characterized in that a planetary roller extruder (10) without kneading disks is used.
5. (original) The method in accordance with claim 2, characterized in that the number of revolutions of the central spindle (14) of the planetary roller extruder (10) is set in such a way that the dwell time in the extruder (10) of a pharmaceutical mixture to be extruded is approximately 0.5 to 2 minutes.
6. (canceled)